DETERMINANTS OF TREATMENT RESPONSE TO SOFOSBUVIR/RAVIDASVIR IN NON-CIRRHOTIC CHRONIC HEPATITIS C PATIENTS: A NESTED CASE-CONTROL ANALYSIS FROM THE EASE TRIAL

Authors:
Muhammad Radzi AH[1], Noor Syahireen M[1], Mohd Azri MS[1], Shahrul Aiman S[1], Nor Asiah M[2], Chan HK[1].

[1] Clinical Research Center, Hospital Sultanah Bahiyah, Alor Setar, Ministry of Health, Malaysia.
[2] Sector for Evidence-Based Healthcare, National Institutes of Health, Ministry of Health, Malaysia

Background:
The EASE trial recently demonstrated that an 8-week regimen of sofosbuvir/ravidasvir was non-inferior to a 12-week regimen in achieving sustained virologic response 12 weeks post-treatment (SVR12) among non-cirrhotic hepatitis C virus (HCV) patients. This nested case-control study aimed to determine whether factors other than treatment duration influence treatment outcomes.

Methods:
Participants included all individuals from the EASE trial who completed either 8- or 12-week treatment and had available SVR12 data. Cases were defined as those achieving SVR12, and controls as those who did not. Multiple logistic regression was conducted on 305 eligible participants to evaluate associations between SVR12 and baseline characteristics, including demographics, HCV genotype, baseline viral load, HIV status, drug use history, and adherence. Adjusted odds ratios (aORs) and 95% confidence intervals (CIs) were reported.

Results:
Of the 305 participants, 285 (93.4%) achieved SVR12, while 20 (6.6%) did not. No baseline variable was significantly associated with treatment response. This included treatment duration (aOR for 8 weeks vs. 12 weeks: 1.05; 95% CI: 0.39–2.83; p=0.919), HCV genotype (aOR for genotype 3 vs. others: 5.04; 95% CI: 0.96–26.61; p=0.057), baseline viral load (aOR for ≥800,000 vs. <800,000 IU/mL: 1.11; 95% CI: 0.38–3.24; p=0.849), HIV co-infection (aOR for HIV positive vs. HIV negative: 2.67; 95% CI: 0.25–28.39; p=0.416), and drug use history (aOR: 1.31; 95% CI: 0.30–5.68; p=0.715). High adherence (≥90%) was reported in 99.3% of the participants but was not significantly associated with SVR12 (aOR: 0.10; 95% CI: 0.01–1.37; p=0.084).

Conclusion:
Among non-cirrhotic HCV patients, SVR12 achievement with sofosbuvir/ravidasvir is unaffected by treatment duration or patient characteristics. These findings support the clinical interchangeability of 8- and 12-week regimens and advocate for a shorter, cost-effective course to enhance treatment accessibility in decentralized and resource-limited settings.

Disclosure of Interest Statement:
This study was funded by the Ministry of Health Malaysia and Drugs for Neglected Diseases Initiative (DNDi). Pharco Pharmaceuticals provided study medications. The funding source had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The authors had full access to all study data and final responsibility for the decision to submit for publication.